UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,581	07/31/2003	Anne-Marie Rodriguez	0857/70669	5002

7590 05/22/2006

John P. White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER	
HAMA, JOANNE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/632,581	RODRIGUEZ ET AL.	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *4-48,51 and 52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,49,50,53 and 54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 February 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 2-7, 9-12, 25-28, 48-54, in the reply filed on February 27, 2006 is acknowledged. The traversal is on the ground(s) that the Restriction Requirement is improper in its entirety (Applicant's response, pages 6-9). The argument is not persuasive as follows. Applicant has indicated the inventions of Groups I-VII are not independent (Applicant's response, page 7, bottom to page 8, 1st parag.). In response, the Examiner has not indicated that the Inventions were independent. Rather, the Examiner has indicated that the Inventions were distinct and did not determine that the Inventions were independent (Restriction, October 20, 2005, page 4). The Examiner has determined that Inventions I and II were not independent because the cells of Invention I could be used to generate the transgenic cells of Invention II. However, the cells were distinct because the cells of Inventions I and II have different DNA structure, as indicated by the fact that Invention II comprises a transgene. Applicant also indicates that the Examiner has failed to fulfill the two criteria for a proper restriction: 1) the invention must be independent or distinct, and 2) there must be a serious burden on the Examiner if restriction were not required (Applicant's response, page 8, 2nd parag.). In response, the Examiner has determined that there would be a burdensome search as indicated by the fact that a search for a human stem cell is not coextensive with a search for a human stem cell comprising a transgene. Applicant indicates that Groups I-III and V-VIII share the same classification (Applicant's response, page 8, 3rd parag.) and thus the search would not be burdensome. In

response, the Examiner searches databases other than classifications in patents and subsequently, the search using other databases (e.g. PubMed) is burdensome in light of the fact that a word search for "transgenic human stem cell" is not coextensive with the word search of "human stem cell". Applicant also indicates that that Groups I and II should be examined together and Groups I-VII should be examined together (Applicant's response, pages 6 and 7). Applicant indicates that claim 1 is a linking claim and links Inventions I and II, that should claim 1 be found allowable, the invention of Group II will be examined in the subject application. In the case that Groups I-VII should be examined together, Applicant indicates that in MPEP§ 821.04, "if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined." In response, applicant indicates correct practice for rejoining inventions; however, the linking claims and products are not allowable. The requirement is still deemed proper and is therefore made FINAL.

Claims 8, 13-24, 29-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 27, 2006.

Claims 1-7, 9-12, 25-28, 48-54 are under consideration.

Specification

> 37 CFR 1.821(d) states: "[w]here the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description of claims, even if the sequence is also embedded in the text or the description or claims of the patent application.

The nucleotide sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). Page 29 of the specification comprises sequences of primers. SEQ ID NOs. must be assigned to these sequences. It is noted that sequences provided in computer readable format (CRF) and on paper and a statement indicating that the sequences on CRF and paper are the same were filed by Applicant on July 19, 2004. However, there is no indication to what these filed sequences correspond to. If the paper sequence listing and CRF include the sequences on page 29, amendment of the specification to include the appropriate SEQ ID NOs will place this application in compliance with 37 CFR 1.821-1.825. If these sequences are not part of the sequence listing, new sequence listings must be filed, see the attached Notice to Comply.

Appropriate correction is required.

The absence of proper sequence listing did not preclude the examination on the merits however, **for a complete response to this office action, applicant must submit the required material for sequence compliance.**

Claim Objections

Claims 4-7, 9-12, 25-28, 48, 51, 52 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 4-7, 9-12, 25-28, 48, 51, 52 have not been further treated on the merits.

Subsequently, claims 1-3, 49, 50, 53, 54 are under examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 49, 50, 53, 54 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to adult multipotent human stem cells. The claims, as they read, encompass cells which have not seen "the hand of man". Using the words "isolated" or "cultured" to describe the cells would be remedial.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 53, 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 53 use the term, "significant telomerase activity." It is unclear what metes and bounds are envisioned by "significant." Claims 2, 3, 54 depend on claims 1 and 53 and thus have been included in the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 49, 50, 53, 54 rejected under 35 U.S.C. 102(b) as being anticipated by Katz et al., PCT Publication No. WO 00/53795, Publication date, September 14, 2000.

Katz et al. teach human lipo-derived stem cells (Katz et al., Example 1). Katz et al. teach that these stem cells can differentiate into adipocytes, osteocytes, myocytes, or chondrocytes (see table on page 18) and that the telomerase activity was similar to that exhibited by previously reported human stem cells (Katz et al., page 18, 1st parag.).

It is noted that while Katz et al. do not specifically teach that the cells have a HLA class I negative phenotype, a normal karyotype, a capacity to become quiescent, and a

capacity for self-renewal preserved for at least 130 population doublings, and following quiescence, exhibits the phenotypes of being HLA class I negative, HLA class II negative, CD3 negative, CD13 positive, LIF-R negative, Oct-4 positive, Rex-1 positive, ABCG2 positive, has a normal karyotype, and significant telomerase activity and has immunoprivileged behavior in vivo and a capacity to migrate in the undifferentiated state, these characteristics would be inherent to the cells isolated by Katz et al. Similarly, cells that have a HLA Class I negative phenotype, a normal karyotype, a self-renewal capacity that is preserved for about 40 to 60 population doublings, is not capable of becoming quiescent, and its proliferation rate is not affected by LIF, these characteristics would be inherent to the cells isolated by Katz et al. It is presumed that the cells taught by Katz et al. would inherently have these characteristics because Katz et al. teach that they behave like human stem cells: they have telomerase activity and have the ability to differentiate into the same cell types as the claimed cells.

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195

USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Claims 1-3, 49, 50, 53, 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Zuk et al., 2001, Tissue Engineering, 7: 211-228, see IDS.

Zuk et al. teach that human processed lipoaspirate (PLA) cells were obtained from liposuction procedures. Zuk et al. teach that the cells differentiate into adipogenic, osteogenic, chondrogenic, and myogenic lineages (Zuk et al., page 217-222).

It is noted that while Zuk et al. do not teach that the cells have a HLA class I negative phenotype, a normal karyotype, a capacity to become quiescent, and a capacity for self-renewal preserved for at least 130 population doublings, and following quiescence, exhibits the phenotypes of being HLA class I negative, HLA class II negative, CD3 negative, CD13 positive, LIF-R negative, Oct-4 positive, Rex-1 positive, ABCG2 positive, has a normal karyotype, and significant telomerase activity and has immunoprivileged behavior in gvivo and a capacity to migrate in the undifferentiated state, these characteristics would be inherent to the cells isolated by Katz et al. Similarly, cells that have a HLA Class I negative phenotype, a normal karyotype, a self-renewal capacity that is preserved for about 40 to 60 population doublings, is no capable of becoming quiescent, and its proliferation rate is not affected by LIF, these characteristics would be inherent to the cells isolated by Zuk et al. It is presumed that the cells taught by Zuk et al. would inherently have these characteristics because Zuk et al. teach that they behave like human stem cells as have the ability to differentiate into

the same cell types as the claimed cells. Further, Zuk et al. teach method steps that are similar to that disclosed in the specification.

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

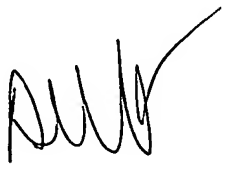
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JH



Application No.:
10/632,581

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other: _____

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY